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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/602,351	06/23/00	FINCK	B 2945-A

DIANA K SHEINESS
IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE WA 98101

HM12/1001

EXAMINER

ROMEO, D

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/602,351

Applicant(s)
Finck et al.

Examiner
David Romeo

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 Jun 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1647

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1, to the extent that they are drawn to a method of treating ordinary

5 psoriasis comprising administering a soluble TNF receptor, classified in class 514, subclass 12.

II. Claim(s) 1-13, to the extent that they are drawn to a method of treating ordinary

psoriasis comprising administering TNFR:Fc, classified in class 424, subclass 178.

III. Claim(s) 14, to the extent that they are drawn to a method of treating cervicogenic

10 headaches comprising administering a soluble TNF receptor, classified in class 514, subclass 12.

IV. Claim(s) 14, to the extent that they are drawn to a method of treating multicentric

reticulohistiocytosis comprising administering a soluble TNF receptor, classified in class 514, subclass 12.

15 V. Claim(s) 14, to the extent that they are drawn to a method of treating chronic

obstructive pulmonary disease comprising administering a soluble TNF receptor, classified in class 514, subclass 12.

Art Unit: 1647

- VI. Claim(s) 14, to the extent that they are drawn to a method of treating engraftment syndrome comprising administering a soluble TNF receptor, classified in class 514, subclass 12.
- 5 VII. Claim(s) 14, to the extent that they are drawn to a method of treating sporadic inclusion body myositis comprising administering a soluble TNF receptor, classified in class 514, subclass 12.
- VIII. Claim(s) 14, to the extent that they are drawn to a method of treating hypertrophic scarring comprising administering a soluble TNF receptor, classified in class 514, subclass 12.
- 10 IX. Claim(s) 14, to the extent that they are drawn to a method of treating abdominal aortic aneurism comprising administering a soluble TNF receptor, classified in class 514, subclass 12.
- X. Claim(s) 14, to the extent that they are drawn to a method of treating lymphangioleiomyomatosis comprising administering a soluble TNF receptor, classified in class 514, subclass 12.
- 15 XI. Claim(s) 14-15, to the extent that they are drawn to a method of treating cervicogenic headaches comprising administering TNFR:Fc, classified in class 424, subclass 178.

Art Unit: 1647

XII. Claim(s) 14-15, to the extent that they are drawn to a method of treating multicentric reticulohistiocytosis comprising administering TNFR:Fc, classified in class 424, subclass 178.

5 XIII. Claim(s) 14-15, to the extent that they are drawn to a method of treating chronic obstructive pulmonary disease comprising administering TNFR:Fc, classified in class 424, subclass 178.

XIV. Claim(s) 14-15, to the extent that they are drawn to a method of treating engraftment syndrome comprising administering TNFR:Fc, classified in class 424, subclass 178.

10 XV. Claim(s) 14-15, to the extent that they are drawn to a method of treating sporadic inclusion body myositis comprising administering TNFR:Fc, classified in class 424, subclass 178.

XVI. Claim(s) 14-15, to the extent that they are drawn to a method of treating hypertrophic scarring comprising administering TNFR:Fc, classified in class 424, subclass 178.

15 XVII. Claim(s) 14-15, to the extent that they are drawn to a method of treating abdominal aortic aneurism comprising administering TNFR:Fc, classified in class 424, subclass 178.

Art Unit: 1647

XVIII. Claim(s) 14-15, to the extent that they are drawn to a method of treating

lymphangioleiomyomatosis comprising administering TNFR:Fc, classified in
class 424, subclass 178.

XIX. Claim(s) 16, to the extent that they are drawn to a method of treating pulmonary

5 fibrosis comprising administering an indeterminate TNF- α inhibitor, classified in
class indeterminate, subclass indeterminate.

XX. Claim(s) 16, to the extent that they are drawn to a method of treating systemic

sclerosis comprising administering an indeterminate TNF- α inhibitor, classified in
class indeterminate, subclass indeterminate.

10 XXI. Claim(s) 16-17, to the extent that they are drawn to a method of treating

pulmonary fibrosis comprising administering TNFR:Fc, classified in class 424,
subclass 178.

XXII. Claim(s) 16-17, to the extent that they are drawn to a method of treating systemic

sclerosis comprising administering TNFR:Fc, classified in class 424, subclass 178.

15 XXIII. Claim(s) 18, to the extent that they are drawn to a method of treating cystic

fibrosis comprising administering TNFR:Fc, classified in class 424, subclass 178.

2. The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1647

a. The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes: I and each of II-XXIII;

II and each of III-XXIII; III and each of IV-XXIII; IV and each of V-XXIII; V and each of

5 VI-XXIII; VI and each of VII-XXIII; VII and each of VIII-XXIII; VIII and each of IX-XXIII;

IX and each of X-XXIII; X and each of XI-XXIII; XI and each of XII-XXIII; XII and each of XIII-XXIII; XIII and each of XIV-XXIII; XIV and each of XV-XXIII; XV and each of

XVI-XXIII; XVI and each of XVII-XXIII; XVII and each of XVIII-XXIII; XVIII and each of XIX-XXIII; XIX and each of XX-XXIII; XX and each of XXI-XXIII; XXI and each of

10 XXII-XXIII; XXII and XXIII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required
15 are not coextensive, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1647

6. This application contains claims directed to the following patentably distinct species of the claimed invention: compounds in claims 7, 9, 10, 16, 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, II, XIX-XXIII are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15 Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1647

7. This application contains claims directed to the following patentably distinct species of the claimed invention: the therapies in claim 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, II is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1647

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

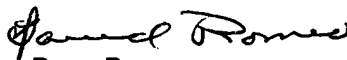
ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

SEPTEMBER 29, 2001